Statement of

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Good morning Chairman Stupak, Ranking Member Whitfield, Chairman Dingell and members of the Subcommittee. I thank you for your interest and allowing me this valuable opportunity to speak on behalf of my friends and colleagues at the Winchester Engineering and Analytical Center (WEAC) and the citizens of this nation at this critical juncture at a time when the Office of Regulatory Affairs (ORA) is redefining its commitment to its mandated public health mission. My name is Charles Clavet, and I have worked for the past 16 years as a microbiologist at the Winchester Engineering and Analytical Center which is located in Winchester, Massachusetts and is one of thirteen field laboratories operated by the Office of Regulatory Affairs (ORA). It is an FDA owned facility that costs nothing in terms of rent or lease payments. I would like to take this time to briefly describe the many unique public health functions and capabilities WEAC possesses and to discuss openly our concerns and questions regarding the impending laboratory closures.

The closing of WEAC and subsequent loss of virtually all analysts will have an impact on ORA's ability to continue to fulfill its public health mission. In order to comprehend the full impact of losing this facility and personnel it is imperative that the wide range of WEAC' capabilities be made known. In fact, the list of capabilities and interactions is so extensive, and impossible to cover in the time allotted, that I would like to submit for the record several documents that elaborate upon WEAC's immense contribution to ORA's mission.

WEAC is a truly unique laboratory asset with many experienced, motivated scientists (radiochemists, chemists, biologists, microbiologists and engineers) working in harmony to provide specialized analytical capabilities utilizing their respective disciplines. We are an American Association for Laboratory Accreditation (A2LA) certified ORA field laboratory that specializes in regulatory testing of foods for radionuclides and the analyses of medical devices for safety and efficacy. This accreditation would not be easily transferable to another location without the associated movement of the personnel currently performing this work. WEAC's laboratory provides services to the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Criminal Investigations (OCI), the Center for Devices and Radiological Health (CDRH), states and local governments with a legacy of proven performance in fulfilling ORA's public health mission while continuously enduring budget constraints.

Radiochemical Capabilities/Responsibilities

- WEAC is the only FDA facility that has full analytical capability and expertise for the analysis of foods for the detection of gamma, beta and alpha contamination.

- WEAC holds FDA's only Nuclear Regulatory Commission (NRC) license and handles the radiation equipment, calibration and radiation safety training for all ORA field personnel.
- WEAC's radionuclide laboratory has state-of-the-art equipment and personnel. Our site and processes are A2LA accredited and significant quality systems are in place to ensure that they are legally defensible.
- WEAC is the sole laboratory providing food expertise to the CDC, EPA, DOD, USDA and the Department of Homeland Security under the Interagency Consortium of Lab Networks agreement (ICLN).
- WEAC has Memorandum of Understanding (MOU) with USDA/FSIS for the radionuclide analysis of USDA regulated products in case of emergency.
- WEAC also has a MOU with the United States Department of the State and the Department of Energy.
- If WEAC closes the NRC license will have to be reestablished and all current radiological arrangements and agreements will be canceled.
- WEAC radionuclide laboratory has effectively responded to food emergencies resulting from Chernobyl, Three Mile Island, Mass. Bay Foul Area Survey, polonium (Po)-210 static eliminators in pharmaceutical products, nuclear reactor scares and the recent polonium (Po)-210 poisoning in the UK that quickly became worldwide in scope.
- In the recent polonium (Po)-210 incident, CDC asked WEAC for assistance in development of a food method for Po-210 sample analysis.

- WEAC was the only US regulatory lab that participated in the International Atomic Energy Agency (IAEA) polonium (Po)-210 proficiency to assess laboratory readiness and passed all acceptance criteria.
- WEAC is the lead laboratory for the Food Emergency Response Network (FERN) laboratories in response to radiological emergencies and is actively expanding its capabilities for detecting all radionuclides of greatest concern through research and method development.
- WEAC prepares proficiency samples and provides methods and training to the various FERN laboratories.

Microbiological Method Development- FERN

- WEAC conducts research at the University of New Hampshire Biosafety Level-3 facility in support of ORA's Microbiological FERN program.
- WEAC's research has contributed to the development of a method for the detection of Yersinia pestis (the plague bacterium) in foods and participated in a collaborative study for the automated detection of Yersinia pestis.
- The lab is currently preparing to conduct studies with Francisella tularensis, another select agent, for the food defense workgroup.

WEAC Laboratory Support for CDRH Programs

In addition to our radionuclide specialty, WEAC is the servicing laboratory for the Center for Devices and Radiological Health (CDRH) providing a wide range of

engineering and analytical capabilities (microbiological, biological and chemical) for medical device evaluation. WEAC is the only laboratory that employs engineers and regularly sends them to China to inspect production facilities of non-ionizing radiation emitting products (lasers, microwave ovens and televisions. No other ORA laboratory provides this unique combination of scientific disciplines working in concert. WEAC engineers have conducted numerous research projects for CDRH and the results have been used to set international standards and methods.

Historically, CDRH has relied heavily on the scientific and regulatory expertise of WEAC and anticipates both continuing and growing needs into the foreseeable future. For this reason, CDRH has requested that ORA commit a single physical laboratory site to the CDRH work plan and method development goals.

It appears that ORA has determined that the condition of the WEAC facility is the reason for closing the building. Incredibly, during the whole ORA transformation process no member of the Transformation Leadership Team (TLT) has surveyed the physical WEAC facility to examine the equipment and its environment. Within the last year the Associate Commissioner of Regulatory Affairs (ACRA) came to Boston and never visited WEAC. Yet, the decision has been made in Rockville, MD, and ORA continually sites an outdated study as the evidence for the closure. There have been major improvements to the facility over the past three to four years. Has this been considered?

We are confused. The continuous flow of rhetoric does not agree with the concomitant actions. On one hand we have been praised for our commitment, our dedication, and the knowledge and skills that we possess. There is talk about the need for retention and recruitment. Yet, when 100 new positions were recently made available

personnel at the affected labs were excluded from applying for these jobs. One high level ORA manager from the TLT committee states that, “we are committed to going outside the agency”, and the FDA spokesperson says, “Ultimately we want new people and new equipment”. Why was this done? I can tell you Mr. Chairman, the puzzlement I have expressed is not solely mine but is shared by my colleagues and peers at WEAC. I have discussed this with the elected leaders of NTEU, our union at WEAC, and with many of the dedicated professionals I work with. None of us see any merit in the lab closure proposal. NTEU officers have been in communication with employees at the other labs proposed for closure, and their views are the same.

In conclusion, as I prepared this testimony I began to realize that it was going to be very difficult to articulate and convey the complete picture of WEAC and its personnel in five minutes. I came to the realization that I could only highlight some of its responsibilities, contributions and interactions that occur on a daily basis as this group of dedicated scientist carry out ORA’s public health mission. The more time that I spent on trying to condense the information the more puzzled I became. Why would anyone want to close this facility? At this point in time Mr. Chairman and members of this subcommittee, WEAC’s fate is in your hands. I hope that you can find a way to allow WEAC to continue its vital public health service to the citizens of this nation. I would be happy to answer any questions members of the committee may have.